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09/687,384	10/13/2000	Timothy G. Dinan	99,829-A	7338

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EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/687,384
Filing Date: October 13, 2000
Appellant(s): DINAN ET AL.

Adriana L. Burgy
For Appellant

EXAMINER'S ANSWER

A handwritten signature, possibly "N", in the bottom right corner of the page.

This is in response to the appeal brief filed 27 January 2005.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is deficient because while appellant is correct in identifying the affinity for 5HT_{1a} receptors, the method of the invention is a method of treatment comprised of administering a composition comprising S(-) pindolol or salts thereof to treat gastrointestinal diseases.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1 and 4-7 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

Claim 1 contains substantial errors as presented in the Appendix to the brief.

Accordingly, claim 1 is correctly written below:

1. A method for treating gastrointestinal disease comprising administering an effective amount of S(-) pindolol, or a salt thereof, to a subject in need thereof.

(9) Prior Art of Record

Buzas et al., RO 92436 September 30, 1987

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(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buzas et al. RO 92436.

The claims are drawn treatment of gastrointestinal disease comprising administering and effective amount of S(-) pindolol or a salt thereof to a subject in need thereof.

Dependent claims are drawn to a rapid release dosage form and a slow release dosage form.

Buzas et al. teach a composition comprising a carbonic anhydrase inhibitor and a beta blocker such as pindolol (see abstract) to treat gastritis, gastro-duodenitis and gastro-duodenal ulcers.

It does not teach S (-) pindolol. However, absent factual evidence to the contrary, the pindolol cited in the reference is a racemic mixture, which would include the S(-) pindolol in the claims. Further, since it is known that pindolol is an antagonist of 5HT1a it is reasonable to expect that S(-) pindolol would also have those properties. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Regarding the rapid release formulation and the slow release formulation, it would have been obvious to treat an acute gastrointestinal attack with a rapid release agent motivated by the fact

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that a rapid release of the active agent would permit fast relief of acute pain associated with a gastrointestinal disorder. In a chronic gastrointestinal disease, it would have been obvious to administer S (-) pindolol in a slow release matrix motivated by the fact that a slow release matrix would release the agent slowly, thus alleviating a chronic condition. Claim 7 is drawn to treatment of nausea. Since nausea is a disorder associated with the motility of the gastrointestinal system, it would have been obvious to treat nausea since Buzas et al. teach that, *interalia*, pindolol reduces gastric secretions (page 5, lines 31-40). Thus reducing the gastric secretions (acid) would inhibit nausea.

(11) Response to Argument

Appellant argues that the criteria have not been met by the rejection of record. Appellant further argues that the transitional phrase "comprising" has been amended to "consisting essentially of". The examiner wishes to point out that the amendment was proposed after the case was finally rejected and the amendment has not been entered. Appellant disagrees with the examiners assertion that Buzas teaches use of pindolol alone can treat gastrointestinal disease, but has a greater effect when administered together with a carbonic anhydrase inhibitor. Appellant has attempted to amend the claim to recite the transitional phrase "consisting essentially of" to limit the claim. Although appellant's arguments are directed to a version of the claims that was **never entered into the case**, The examiner has taken the following from the MPEP § 2111.03 [R-2] "the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel

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characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." If the applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USP 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)." It does not appear that the addition of the carbonic anhydrase inhibitor of the prior art would materially change the characteristics of the appellant's invention since both agents would treat gastrointestinal disease. See Buzas et al., table 3, page 8, where the activity of some beta-adrenergic blockers were tested on the production of hydrochloric acid and the activity of gastric mucosa in patients with duodenal ulcers. Pindolol was dosed alone (no carbonic anhydrase inhibitor) for 10 days at 3 mg per dose. Appellant disagrees with the examiners conclusion that synergy is the interaction of two or more treatments such that their combined effect is greater than the sum of the individual effects observed when each treatment is administered alone, yet appellant admits that pindolol was administered alone (see page 14 of appellants arguments) wherein pindolol was administered alone and flow of hydrochloric acid was measured. Appellants only argument was that the pindolol did not differ from the control (9.87 ± 2.71 of control vs. 7.98 ± 1.17 for pindolol). In response, the results did differ, albeit, not

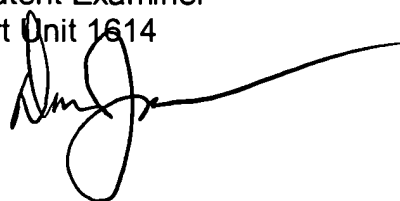
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significantly, however, the instant claims do not recite the percent efficacy of the pindolol, nor a dose that would be more effective over the 3mg per day administered by Buzas.

For the above reasons, it is believed that the rejections should be sustained.

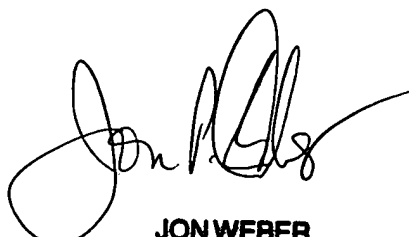
Respectfully submitted,

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Patent Examiner
Art Unit 1614




dj
April 29, 2005

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